

# PATENT COOPERATION TREATY

## PCT


### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 22 NOV 2005

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Applicant's or agent's file reference		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/IL2004/000870		International filing date (day/month/year) 20.09.2004	Priority date (day/month/year) 21.09.2003	
International Patent Classification (IPC) or national classification and IPC A61F5/055, A61F5/37				
Applicant HADASIT MEDICAL RESEARCH SERVICES AND ....et Al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  10.07.2005		Date of completion of this report  22.11.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Germano, A  Telephone No. +31 70 340-4202		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

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**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-22 as originally filed

**Claims, Numbers**

1-15 as originally filed

**Drawings, Sheets**

1-43 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12-15

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 12-15

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-11 .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-11
Inventive step (IS)	Yes: Claims	
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. Claims 12 and 13-15 were not searched in view of Art. 17(2)(a)(ii) and 17(2)(a)(I) PCT respectively, see also Rules 6.2(a) and 39.1(iv). Therefore a substantive examination for these claims is not possible.
- 1.1 It should also be considered that claim 12 is so unclear, that no meaningful opinion can be formed on novelty, inventive step or industrial applicability of the matter of the claim, see Art. 34(4)(a)(ii) PCT, while claims 13-15 refer to matter, namely methods of treatment of the human or animal body, for which the substantive examination is not required, see Art. 34(4)(a)(I) and Rule 67.1(iv) PCT.

**Re Item IV**

**Lack of unity of invention**

2. The application refers to two different inventions and therefore fails to meet the requirements of Rule 13.1 PCT

The two different inventions referred to in the application are:

- a) a cervical collar comprising a rigid motion restricting frame and a jaw clasp, according to claims 1 to 5, and
  - b) a jaw clasp according to claims 6 to 11.
- 2.1 According to Rule 13.1 PCT, an International Application may relate only to one invention, or to a group of inventions (generally defined in different independent claims) so linked as to form a single general inventive concept.

In the second case, the concept linking the inventions finds expression in the different independent claims according to the different inventions in terms of the same or corresponding technical special features, wherein the expression "technical special

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features" means the features which involve an inventive contribution over the prior art, see Rule 13.2 PCT.

- 2.2 In the present case the same or corresponding technical feature of claims 1 and 6 is: "a jaw clasp."

This feature is well known and is disclosed in several documents of the available prior art, see for example US-A-5 575 763 or US-A-6 267 741, and therefore is not only not inventive but even not new.

The remaining features of claims 1 and 6 are different and have different purposes, and therefore are not "corresponding features" within the meaning of Rule 13.2 PCT

Therefore no inventive concept links the inventions according to claims 1 and 6 and the application does not meet the requirements of Rule 13.1 PCT.

- 2.3 However, in view of Rule 68.1, no extra fees are requested for extending the substantive examination to the two groups of claims cited above.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

3. It appears that the subject-matter of independent claim 1, insofar as it may be understood (see Item VIII) is not new. The same apply to independent claim 6.

- 3.1 The document US-A-5 575 763, see figs. 2-5 and col. 4, line 9 to col. 6, line 12 (the signs refer to said document while the wording is that of claim 1) discloses;

"a cervical collar "useful" for maintaining the airways in trauma patients having head and neck immobilized open, said collar comprising:

- a) a rigid motion-restricting frame (2) "attached to the head"
- b) a jaw clasp (1) "attached to the jaw",

The further reference of claim 1, namely: "the collar (2) is simultaneously restricting the motion of the head and neck while allowing motion of the jaw to maintain open the airways" merely defines a purpose of the device and does not contain any technical feature which may distinguish the claimed device from the prior art. Besides this fact, there is no doubts that the devices disclosed in the prior art not only restrict the motion of head and neck, but also allow the airways to be maintained open. If that were not the case, then the patient would be suffocated by the devices.

The same considerations apply for the documents US-A-5 003 968, US-A-4 854 306, US-A-4 643 174 and US-A-6 267 741, which disclose in combination all of the features of claim 1 as well.

Therefore the subject-matter of claim 1 is not new and does not comply with the requirements of Art. 33(2) PCT.

3.2 The same document US-A-5 575 763 discloses, see the same references cited at point 3.2 above:

"a jaw clasp (1) "useful" for performing the jaw-thrust manoeuvre motion of the jaw to maintain open the airways comprising:

- a) a plurality of movable fitting elements (1a, 1b, 4 etc) adapted to fit the jaw (1) tightly, and
- b) a plurality of movable elements (5, 7, 7a ) adapted to move the jaw.

This disclosure corresponds to the subject-matter of claim 6, which therefore is not new.

Documents US-A-5 003 968, US-A-4 854 306, US-A-4 643 174 and US-A-6 267 741 are also detrimental for the novelty of claim 6.

Therefore the subject-matter of claim 6 is not new and does not comply with the requirements of Art. 33(2) PCT.

4. The features of dependent claims 2 to 5 and 7 to 11 are also disclosed, in



combination with the features of claims 1 and 6 respectively, in said prior art.

Therefore the subject-matter of said claims is not new as well and does not meet the requirements of Art. 33(2) PCT.

- 4.1 Also the disclosure of the other documents cited at point 3.2 appear to be prejudicial for the novelty of the dependent claims of the application.
5. The device described in independent claims 1 and 6 and their dependent claims is industrially manufacturable. Therefore the claims meet the requirements of Art. 33(4) PCT.

**Re Item VII**

**Certain defects in the international application**

6. Contrary to the requirements of Rule 6.3(a)(I) and (ii), independent claim 6 is not shaped in the two part form. However, taking into account that all of the features of both independent claims are described in the prior art, it appears that new independent claims should have been formulated including in the preamble at least all of the features of present claims 1 and 6.
7. The features of the claim/s are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
8. In order to meet the requirements of Rule 5.1(a)(ii), the description should have been drafted so as to acknowledge the document disclosing the closest prior art (see for example US-A-5 575 763) and briefly resume it.
9. In order to comply with the requirements of Rule 5.1(a)(ii) the description should have disclosed the invention as claimed.

**Re Item VIII**

**Certain observations on the international application**

10. The wording of claim 1 is not clear, Art. 6 PCT. In particular it is not possible to understand the meaning of the references:

- a) "useful for maintaining the airways in head and neck immobilized trauma patients open",
- b) "a rigid motion-restricting frame (2) attached to the head", and
- c) "a jaw clasp attached to the jaw".

In particular the definition "useful for...." does not define unambiguously the purpose of the device.

The references b) and c), insofar as they define features of the combination of the device with other items (head, jaw) which are not part of the device, are also unclear.

10.1 The characterizing portion of claim 1 merely states the purpose of the collar when in use and does not contain any technical feature relevant for said use. The attempt of defining the matter for which the protection is sought in such a way involves a lack of clarity, contrary to the requirements of Art. 6. PCT.

11. The use of different definitions to define the features of the invention in the claims and in the description is such that the requirements of clarity of Art. 6 PCT are also not met because of this inconsistency.

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